

CLAIMS

1. Method for preparing monodisperse biodegradable microspheres comprising the steps of:

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a) preparing an emulsion comprising at least one polymer phase, which comprises an active ingredient, and at least one aqueous phase, the viscosity of the organic phase and the aqueous phase having a ratio of from 0.1 to 10;

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b) subjecting the emulsion obtained to controlled laminar shearing;

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c) removing the solvent from the polymer phase; and

d) isolating the microspheres so obtained.

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2. Method according to claim 1, wherein the microspheres are constituted in majority by a biodegradable polymer.

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3. Method according to claim 2, wherein the biodegradable polymer is selected from poly(α -hydroxy) acids, the aliphatic polyesters of poly(α -hydroxy acids), of poly(ϵ -caprolactones)-PCL, of polydioxanones - PDO, polyorthoesters, polyanhydrides, polycyanoacrylates, polyurethanes, polypeptides or poly(amino acids), modified polysaccharides, cellulose, polycarbonates, polydimethylsiloxanes and poly(vinyl acetates) and their derivatives and copolymers.

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4. Method according to claim 2 or claim 3, wherein the biodegradable polymer is selected from polylactic acids

(PLA), and the copolymers of polylactic acid / polyglycolic acid (PLGA).

5. Method according to any one of claims 1 to 4, wherein
5 the polymer has a molecular weight of from 50 to 500 kDaltons.

6. Method according to any one of claims 1 to 5, wherein
the organic solvent of the organic phase of the emulsion is
10 ethyl acetate.

7. Method according to any one of claims 1 to 6, wherein
the active ingredient is lipid-soluble.

15 8. Method according to any one of claims 1 to 7, wherein
the active ingredient is water-soluble.

9. Method according to any one of claims 1 to 8, wherein
the active ingredient is a peptide or a protein.

20 10. Method according to any one of claims 1 to 9, wherein
the emulsion prepared in step (a) comprises a hydrophilic
active ingredient in combination with a lipophilic active
ingredient.

25 11. Method according to any one of claims 1 to 10, wherein
the organic phase of the emulsion represents from 10 to 60%
by weight relative to the total weight of the emulsion.

30 12. Method according to any one of claims 1 to 11, wherein
the organic phase of the emulsion comprises from 1 to 50%,
preferably from 5 to 30% by weight of polymer.

13. Method according to any one of claims 1 to 12, wherein the organic phase of the emulsion comprises from 1 to 50%, preferably from 5 to 30% by weight of active ingredient.

5 14. Method according to any one of claims 1 to 13, wherein the emulsion is a double emulsion.

15. Method according to any one of claims 1 to 14, wherein the external and/or internal aqueous phase of the emulsion
10 contains at least one stabilizing agent and/or at least one viscosity agent.

16. Method according to any one of claims 1 to 15, wherein the external and/or internal aqueous phase of the emulsion
15 contains at least one stabilizing agent and/or at least one osmolarity agent and/or at least one surfactant and/or at least one buffer agent.

17. Method according to any one of claims 1 to 16, wherein
20 the step of calibration by laminar shearing is carried out in a Couette device.

18. Method according to any one of claims 1 to 17, wherein the step of removing the solvent from the polymer phase is
25 carried out by extraction in water.

19. Use of the microspheres obtainable according to any one of claims 1 to 18, for the administration of active ingredients in the human or animal organism.

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20. Use according to claim 19, wherein the active ingredient is selected from antibiotics, hypolipidaemics, antihypertensives, antiviral agents, beta blockers, bronchodilators, cytostatics, psychotropic agents, hormones,

vasodilators, anti-allergics, analgesics, antipyretics,
antispasmodics, anti-inflammatories, anti-angiogenics,
antibacterials, anti-ulcerants, antifungals, anti-
parasitics, antidiabetics, anti-epileptics, anti-Parkinsons,
5 antimigraines, anti-Alzheimers, anti-acneics, antiglaucomic
agents, anti-asthmatics, neuroleptics, antidepressants,
anxiolytics, hypnotics, normothymics, sedatives,
psychostimulants, anti-osteoporosis agents, anti-arthritis,
anticoagulants, antipsoriasis agents, hyperglycaemics,
10 orexigenics, anorexigenics, anti-asthenics, anticonstipation
agents, antidiarrhoeals, anti-trauma agents, diuretics,
myorelaxants, enuresis medicaments, erection disorder
medicaments, vitamins, peptides, proteins, anticancer
agents, nucleic acids, RNA, oligonucleotides, ribozymes and
15 DNA.